

REMARKS/ARGUMENTS

Claims 2-23 remain pending in this application. Claim 2, 4 and 20 have been amended. Claim 1 has been canceled. New claim 23 has been added. Insofar as the total number of claims remains the same, no fee is due for the added claim.

In response to the Examiner's objections regarding the drawings, replacement drawings are being submitted herewith, along with a marked-up version showing the changes made in red ink. The Examiner indicated that flanges 28 and height h were not included in the drawings. Such references were included in the original drawings and are clearly present in Figures 1 and 2, respectively, of the replacement drawings. Flanges 28a and 28b were labeled as such in Figures 1 and 2 of the original drawings. Furthermore, height h was labeled as such in Figure 2 of the original drawings.

The Examiner also objected to the drawings as not showing the mask and air source, as specified in the claims. New Figure 6 depicts mask 38 and air source 40. Support for this drawing can be found at page 1, paragraph 0007, as well as in the original claims. New paragraphs 0020.1 and 0033.1 have been added to describe Figure 6.

The Examiner objected to paragraph 0012 of the specification which contained a typographical error. Amended paragraph 0012 is submitted herewith to correct the typographical error.

The Examiner rejected claim 20 under 35 U.S.C. 112 as being indefinite insofar as the claimed lacked antecedent basis for the term "said disk." Claim 20 has been amended to remove reference to "said disk."

Claims 1-5, 10 and 12-16 are patentable over Moulton

The Examiner rejected claims 1-5, 10 and 12-16 under 35 U.S.C. 103(a) as being unpatentable over Moulton, U.S. Patent No. 746,869. Insofar as claim 1 has been deleted, and claims 2-5 and 10 now depend from new independent claim 23, the rejection with respect to such claims is now moot. Furthermore, new claim 23 is not obvious over Moulton. Moulton discloses a flexible plate that is configured to be placed between the lips and held in contact with the teeth (col. 2, lines 69-70). Nothing in Moulton discloses or suggests that the plate be adapted to adhere to the interior of the user's lips and/or cheeks. Rather, Moulton teaches away from such a configuration by indicating that the plate should be held in contact with the teeth and gums. Furthermore, the materials recited in Moulton (col. 2, lines 64-71), and referenced by the Examiner, would not adhere to the interior of the user's mouth, and would not seal the user's mouth.

The Examiner has argued that the thicknesses claimed in the present application would have been an obvious matter of design choice. Insofar as a thin disk can enable the disk to better adhere to the interior of the users lips and/or cheeks, it is not simply an obvious design choice to provide a disk of the claimed thickness. Because there is nothing in Moulton to suggest providing a disk configured to adhere to the interior of the user's lips and/or cheeks, there would have been no motivation to provide a disk of the claimed thickness.

Rejected claims 2-5 and 10 depend from independent claim 23. As discussed above, independent claim 1 is patentable over Moulton. As a result, dependent claims 2-5 and 10, which contain all of the limitations of dependent claim 1, are also patentable over Moulton. The Examiner's arguments regarding the additional limitations of claims 2-5 and 10 are moot.

With respect to independent claim 16, as discussed above, there is nothing in Moulton to suggest providing a disk configured to adhere to the interior of the user's lips and/or cheeks. As a result, it would not have been an obvious matter of design choice to replace the materials disclosed in Moulton with a material that naturally adheres to the interior of the user's lips and cheeks.

With respect to claims 12-15, the Examiner indicates that such claims are equivalent in scope to claims 1, 4, 5 and 10, and are included in Moulton. However, the bite block claimed in independent claim 12, from which claims 13-15 depend, is not set forth in any of claims 1, 4, 5 or 10. Thus, claims 12-15 are not equivalent in scope to claims 1, 4, 5 or 10. Moulton in now way discloses or suggests a bite block. As such, independent claim 12 and claims 13-15 which depend therefrom are not unpatentable over Moulton.

Claims 6-9 and 11 are patentable over Moulton in view of Blachly et al.

The Examiner has rejected claims 6-9 and 11 under 35 U.S.C. 103(a) as being unpatentable over Moulton in view of Blachly et al. (U.S. Patent No. 4,270,531), which discloses a bite block assembly. Rejected claims 6-9 and 11 depend from independent claim 23. As discussed above, independent claim 23 is patentable over Moulton. As a result, dependent claims 6-9 and 11, which contain all of the limitations of independent claim 23, are also patentable over Moulton. The Examiner's arguments regarding the additional limitations of claims 6-9 and 11, directed to a bite block, are moot. However, Applicant would like to point out that the bite block (12) of Blachly et al. is U-shaped, having a front and laterally spaced sides extending longitudinally rearwardly and is much wider than 15 mm (Col. 4, lines 1-6, Fig. 2). Furthermore, Blachly et al. attempt to maintain an open airway by using an airway tube (10). The bite block is used to position the airway tube, not to position the user's lower jaw in a

position that maintains an open airway (Col. 2, lines 26-46). In view of the foregoing, claims 6-9 and 11, and claims 12-15 discussed above, are patentable over Moulton, in view of Blachly et al.

Claims 17-19 and 21-22 are patentable over Goldstein in view of Moulton

The Examiner has rejected claims 17-19 under 35 U.S.C. 102(b) as being anticipated by Goldstein (U.S. Patent No. 6,012,455).

Goldstein is directed to a nasal air delivery apparatus which is supported by a dentally stabilized platform. In order to retain the nose mask of the air delivery apparatus in place, a dental anchor (24) is held between the teeth of the user. A platform extends from the dental anchor. The platform supports a connector, which in turn supports the nose mask. The sole purpose of the dental anchor is to anchor the platform which supports and stabilizes the nasal mask in place. The dental anchor disclosed in Goldstein is not configured to prevent air from leaking out of the user's mouth. Furthermore, because Goldstein is solely concerned with supporting and stabilizing the nasal mask, there is no suggestion or motivation in Goldstein to provide a mouthpiece that prevents air from leaking out of the user's mouth. In addition, contrary to the Examiner's assertion, Figure 1 of Goldstein does not disclose or suggest that dental anchor (24) adheres to the interior of the user's lips. Rather, Figure 2 simply depicts the dental anchor within the user's mouth.

The Examiner has rejected claims 21 and 22 over Goldstein in view of Moulton. Claims 21 and 22 depend from independent claim 17. As discussed above, independent claim 17 is patentable over Goldstein. As a result, dependent claims 21 and 22 are also patentable over Goldstein. Insofar as Goldstein and Moulton are directed to different type of inventions with different purposes, the references are not properly combinable. Even if the references were

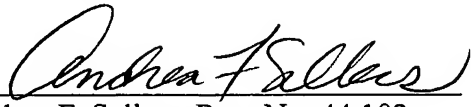
properly combinable, there would be no motivation for one in the art to use the mouthpiece of Moulton in the device of Goldstein, insofar as there is no suggestion or motivation in Goldstein to prevent the ingress of air into the mouth and there is no suggestion in Moulton that the mouthpiece disclosed therein could serve as a support structure. In view of the foregoing, claims 17-19 and 21-22 are patentable over Goldstein in view of Moulton.

In view of the foregoing amendments and remarks, it is respectfully submitted that the claims are now in condition for allowance and eventual issuance. Such action is respectfully requested. Should the Examiner have any further questions or comments which need be addressed in order to obtain allowance, he is invited to contact the undersigned attorney at the number listed below.

Attached hereto is a marked-up version of the changes made to the Specification, Drawings and Claims by the current amendment. The attached page is captioned "Version With Markings to Show Changes Made".

Acknowledgement of receipt is respectfully requested.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Paragraph [0012] has been amended as follows:

[0012] The present invention is directed to a mouthpiece to be used in association with nCPAP systems to prevent leakage from the mouth during nCPAP treatment. The mouthpiece is comprised of a thin flexible disk that fits between the user's lips and teeth and seals the mouth around the interior of the lips to prevent air from escaping. Preferably the disk is made of a material **that [the]** produces a slight adhesion with the inside of the user's lips and cheeks to assist in holding the mouthpiece in place. When used with an nCPAP system, the mouthpiece of the present invention seals the mouth to prevent air from the nCPAP system from leaking out of the mouth, allowing accurate titration of the air pressure needed by the user. Accurate titration using the mouthpiece of the present invention generally results in a lower prescribed pressure, which decreases the side effects of the nCPAP system, makes it easier for the user to exhale and, as a result, leads to increased compliance with the nCPAP treatment program. The mouthpiece may also be used by the user with home nCPAP systems to assure the air is traveling through the airway, and not out of the mouth, to achieve maximum benefits from the nCPAP program.

New paragraphs 0020.1 and 0033.1 have been added.

In the Drawings:

A marked-up version of the drawings showing the changes made thereto is submitted herewith.

In the Claims:

Claim 1 has been canceled.

New Claim 23 has been added .

Claims, 2, 4 and 20 have been amended as follows:

2. (Amended) The mouthpiece of claim 23 [1], wherein the thickness of said disk is less than or substantially equal to 0.5 mm.

4. (Amended) The mouthpiece of claim 23 [1], wherein said disk is comprised of a material that naturally adheres to the interior of the user's lips and cheeks.

20. (Amended) The method for preventing air leakage as claimed in claim 19, wherein said

bite block comprises:

an arm extending substantially perpendicular to the interior surface of said mouthpiece

[disk]; and

a flange extending substantially perpendicular to said arm, wherein the width of said arm

and the width of said flange are less than or substantially equal to 15 mm.



Marked-up Version Showing
Changes

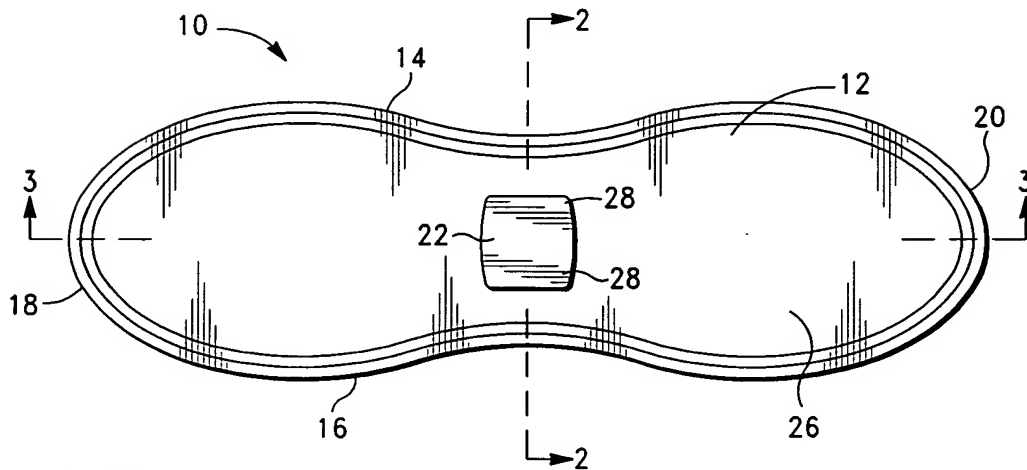


FIG. - 1

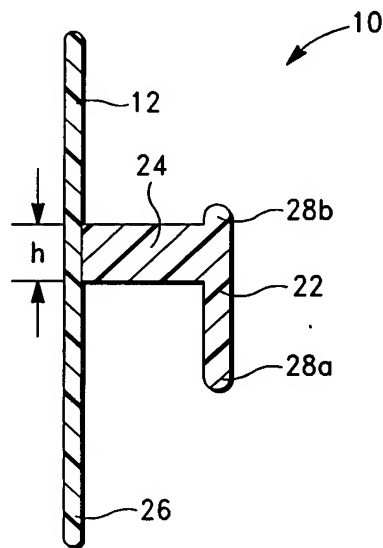


FIG. - 2

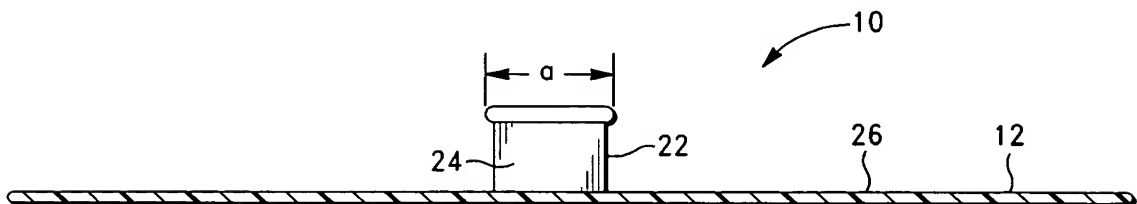


FIG. - 3

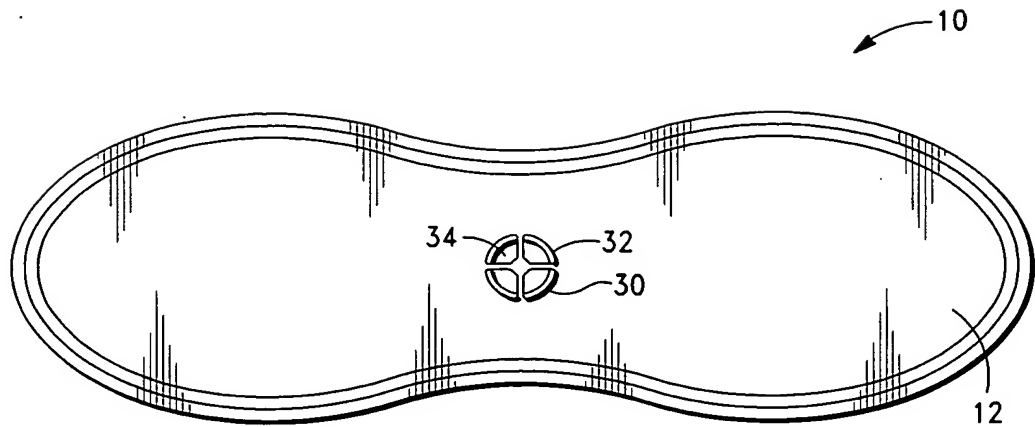


FIG. -4

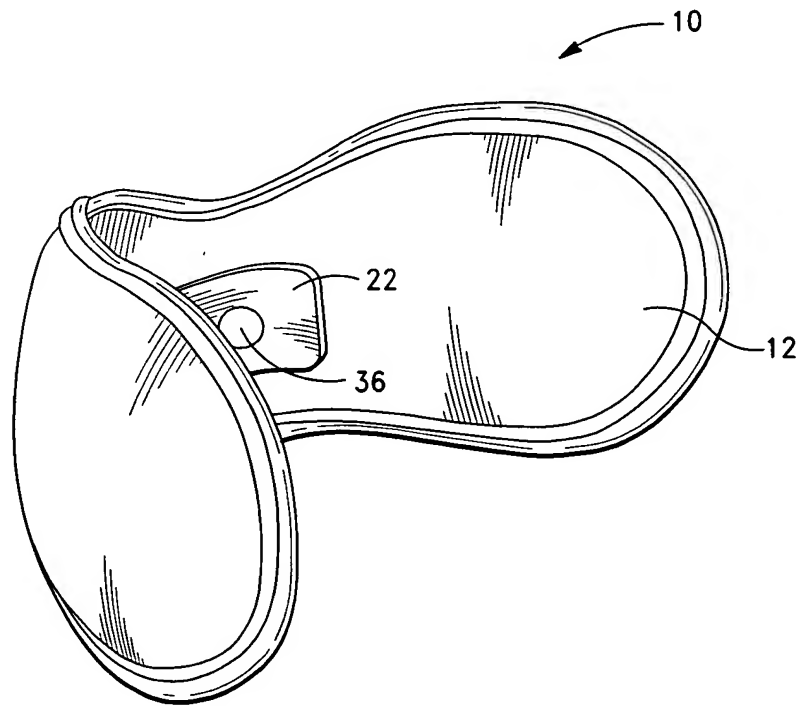


FIG. -5



New Figure



Proposed New
Figure approved
by the examiner
TKM
03/28/03

FIG.-6